UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,863	09/17/2003	**Steven Walak**	10123/00401	8458

7590 06/07/2010

Patrick J. Fay, Esq.
FAY KAPLUN & MARCIN, LLP
Suite 702
150 Broadway
New York, NY 10038

EXAMINER	
WYSZOMIERSKI, GEORGE P	
ART UNIT	**PAPER NUMBER**
1793	

MAIL DATE	DELIVERY MODE
06/07/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte STEVEN WALAK and YIXIN XU

Appeal 2009-002039
Application 10/666,863
Technology Center 1700

Decided: June 7, 2010

Before ROMULO H. DELMENDO, BEVERLY A. FRANKLIN, and JEFFREY B. ROBERTSON, *Administrative Patent Judges*.

DELMENDO, *Administrative Patent Judge*.

DECISION ON APPEAL

Appellants appeal under 35 U.S.C. § 134(a) from a final rejection of claims 1-23 (Appeal Brief filed February 26, 2008, hereinafter "App. Br.," at 1; Final Office Action mailed August 27, 2007). We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

STATEMENT OF THE CASE

Appellants' invention relates "to devices adapted to be implanted in a patient's body and which are subject to cyclic strains" (Specification, hereinafter "Spec." ¶ [0001]). Specifically, the invention is said to include "high strain portions and lesser strain portions, wherein the high strain portions are to be subjected to levels of strain *during use* increased with respect to strain levels in the lesser strain portions" (emphasis added; Spec. ¶ [0005]).

Claims 1 and 16 on appeal read as follows:

> 1. A flexible device comprising a metallic element including high strain portions and lesser strain portions, wherein the high strain portions are to be subjected to levels of strain during use increased with respect to strain levels in the lesser strain portions, the high strain portions comprising a material which is stabilized in a martensite phase when deployed in the body and the lesser strain portions comprise a material which, under the predetermined operating conditions, is in an austenite phase.

> 16. A medical implant comprising a structural element defining a shape of at least a portion of the implant, a super-elastic core portion of the element being primarily formed of Nitinol which, at body temperature, is in a substantially austenitic phase and a fatigue resistant surface portion formed

> of Nitinol which, at body temperature, is substantially Martensite phase stabilized.

(Claims App'x, Reply Brief filed May 20, 2008, hereinafter "Reply Br.," at 13 and 15.)

The Examiner relied upon the following as evidence of unpatentability (Examiner's Answer mailed March 20, 2008, hereinafter "Ans.," 3):

Frantzen	5,514,115	May 7, 1996
Flomenblit	5,964,770	Oct. 12, 1999
Boyle	US 6,923,829 B2	Aug. 2, 2005
Walak (WO '045)	WO 02/36045 A2	May 10, 2002

The Examiner rejected the claims under 35 U.S.C. § 103(a) as follows:

I. Claims 1-8, 15-19, and 22 as unpatentable over Frantzen or WO '045 (Ans. 3-4);

II. Claims 2, 9-13, 20, and 21 as unpatentable over either Frantzen or WO '045, each in view of Flomenblit (Ans. 4-5);

III. Claims 1, 3-8, 14-19, 22, and 23 as unpatentable over Boyle (Ans. 5-6); and

IV. Claims 2, 9-13, 20, and 21 as unpatentable over Boyle in view of Flomenblit (Ans. 6).

ISSUES

Appellants have focused their arguments on the rejections of claims 1 and 16 (App. Br. 3-12). Accordingly, we confine our discussion of the rejections to these two claims. *See* 37 C.F.R. § 41.37(c)(1)(vii).

The Examiner found that Frantzen, WO '045, and Boyle individually describe implantable medical devices made from NITINOL, portions of which, while in use, include a material stabilized in a martensite phase and a material in an austenite phase (Ans. 3, 5). Regarding the limitation "wherein the high strain portions [stabilized martensite phase] are to be subjected to levels of strain during use increased with respect to strain levels in the lesser strain portions [austenite phase]" in claim 1, the Examiner found that the prior art structures "fall within the scope of the invention because it would be possible to subject the former portion to more strain than the latter portion" (Ans. 7-8). The Examiner further asserted that the prior art references disclose or suggest the subject matter of claim 16 (Ans. 8-9).

Appellants' principal argument against Rejections I and III is that, in contrast to claim 1, Frantzen, WO '045, and Boyle do not "show or suggest the *placement* of the martensite and austenite portions in any way related to the strain which is anticipated to be exerted on" the portions of the prior art devices (emphasis added; App. Br. 5, 7, 10). With respect to claim 16, Appellants contend that Frantzen, WO '045, and Boyle do not disclose or suggest a "'super-elastic core portion' separate from a 'fatigue-resistant surface portion'" (App. Br. 6, 7, 10-11). As to Rejections II and IV, Appellants argue that the claims subject to these rejections are patentable for the same reasons in support of claims 1 and 16 and that Flomenblit does not cure the deficiencies in the Examiner's rejections of claims 1 and 16 (App. Br. 8-9, 11-12).

Thus, the dispositive issues are:

(1) Does the absence of disclosure in Frantzen, WO '045, or Boyle as to placement of the device in a body such that the stabilized martensite

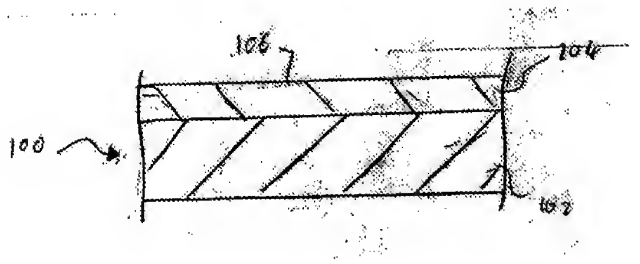
portion and the austenite portion are, during use, subjected to high strain and relatively lesser strain, respectively, preclude the Examiner's rejections of claim 1?

(2) Do the applied prior art references disclose or suggest a "medical implant comprising a structural element defining a shape of at least a portion of the implant," wherein a portion of the element is "a super-elastic core portion" and another portion is a "fatigue-resistant surface portion," as recited in claim 16?

FINDINGS OF FACT ("FF")

1. The Specification acknowledges that NITINOL (an acronym for Nickel Titanium Naval Ordinance Laboratory) has been used to manufacture medical implants (Spec. ¶¶ [0002]-[0004], [0011]).
2. The Specification further states that a "drawback of [NITINOL] . . . is that in certain configurations it is not very resistant to fatigue, i.e. repeated cyclic strains" (Spec. ¶ [0004]).
3. The Specification states that a person of ordinary skill in the art would understand that NITINOL alloys can exist in one of two different temperature-dependent crystal structures: martensitic (at low temperatures); and austenitic (at relatively higher temperatures) (Spec. ¶ [0013]).
4. According to Appellants, "[m]artensite is soft and malleable," whereas "[a]ustenite is a strong and hard phase of the alloy, exhibiting properties similar to those of titanium . . ." (Spec. ¶ [0013]).

5. Appellants explain that, in exemplary embodiments of the invention, "the phase transformation between austenite and martensite in high strain regions of a NITINOL device is prevented" (Spec. ¶ [0021]).
6. Specifically, Appellants state that high strain regions may be stabilized in the martensite phase "by performing certain changes in the chemistry of the high strain regions or by changing internal strains present therein" (Spec. ¶ [0021]).
7. The Specification states that the claimed device includes "a wide range of implantable medical devices" and "that the initial structural element may include structures other than wire, for example, tubing and sheets of material" (Spec. ¶ [0023]).
8. Appellants' Figure 5 is reproduced below:



Appellants' Figure 5 depicts an embodiment of a NITINOL section according to the present invention, wherein section 100 may be a portion of a NITINOL wire or other element of a medical implant, element 106 is the outer surface of the wire subject to increased strain, and 102 is a core portion of untreated austenite alloy (Spec. ¶ [0029]).

9. The Specification does not limit the relative proportions of the stabilized martensite and austenite portions (Spec. ¶ [0021]).
10. The Specification places no limitation on the size of the device or on the area(s) or part(s) of the body into which the device may be implanted (Spec. ¶¶ [0001]-[0040]).
11. The Specification makes it clear to one skilled in the relevant art that the claims are to be construed broadly because "various modifications and changes may be made to the embodiments without departing from the broadest spirit and scope of the present invention as set forth in the claims" (Spec. ¶ [0040]).
12. WO '045 describes endoluminal devices (e.g., vena cava filters, stents, grafts, and/or prostheses) having self-expanding and balloon-expandable properties (p. 1, ll. 4-6).
13. WO '045 discloses that the device may comprise a plurality of filaments including one or more superelastic filaments and one or more plastically deformable filaments (p. 3, ll. 6-7).
14. Figure 3C of WO '045 is reproduced below:

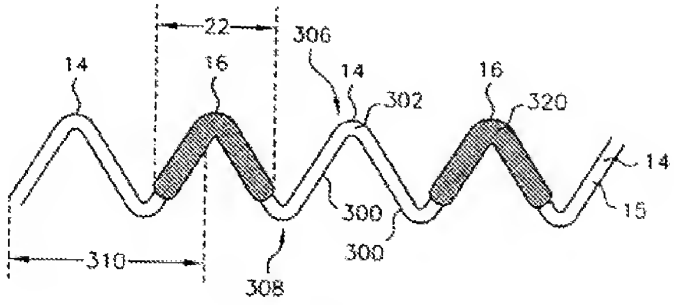


FIG. 3C

Figure 3C of WO '045 represents a side view of a zig-zag stent hoop in a fully-forcibly-expanded configuration, wherein the

device includes a plastically deformable material 320, which may be martensitic NITINOL at use temperature, and a superelastic material (filament 15), which may be austenitic NITINOL at use temperature (p. 3, ll. 20-25; p. 5, ll. 14-15; p. 8, ll. 9-14; p. 10, ll. 12-18; p. 11, ll. 16-27).

15. WO '045 teaches that the device "can . . . be tailored to conform to the anatomy of the lumen in which it is deployed by deforming the plastically deformable section of the device without changing the characteristics of the superelastic section of the device" (p. 17, ll. 4-6).

16. Frantzen describes a housing for intracorporeal use and, in particular, to a housing for a catheter adapted to remove tissue or other material from a body lumen or cavity (e.g., an atherectomy catheter for removal of atheroma from a patient's artery) (col. 2, ll. 27-31).

17. Frantzen teaches that the housing is preferably made from NITINOL alloy, part of which may be in the martensite phase at body temperature (col. 2, ll. 32-44; col. 2, l. 62 to col. 3, l. 34).

18. Frantzen's disclosure at column 3, lines 16-30 makes no mention of a super-elastic core portion of NITINOL in the austenite phase or a fatigue-resistant surface portion of NITINOL in the martensite phase.

19. Boyle teaches an implantable expandable medical device made from a metallic or pseudometallic material having elasto-plastic, shape memory, or pseudoelastic properties (e.g., NITINOL), wherein selected regions of the device are, *in vivo*,

in a martensite phase and selected regions are in an austenite phase (col. 4, l. 46 to col. 5, l. 4; col. 6, l. 65 to col. 7, l. 14).

20. Boyle teaches that the provision of different regions having different properties on the device overcomes the problems of stress and strain imparted on nonlinear vessels (col. 2, ll. 20-43).

21. Boyle further teaches depositing NITINOL on a substrate, which may be cylindrical, forming a pattern on the film, and then forming martensitic regions by heat treatment (which causes nickel precipitation) or altering the chemical stoichiometry (col. 8, l. 52 to col. 9, l. 28).

PRINCIPLES OF LAW

During examination, "the PTO must give claims their broadest reasonable construction consistent with the specification . . . . Therefore, we look to the specification to see if it provides a definition for claim terms, but otherwise apply a broad interpretation." *In re ICON Health and Fitness, Inc.*, 496 F.3d 1374, 1379 (Fed. Cir. 2007).

"[C]hoosing to define an element functionally, *i.e.*, by what it does, carries with it a risk . . . . [W]here the Patent Office [PTO] has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on." *Cf. In re Schreiber*, 128 F.3d 1473,

1478 (Fed. Cir. 1997). *See also In re Best*, 562 F.2d 1252, 1255 (CCPA 1977).

Whether the rejection is based on inherency under 35 U.S.C. § 102 or on obviousness under 35 U.S.C. § 103, "jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products." *Best*, 562 F.2d at 1255.

"Although common sense directs one to look with care at a patent application that claims . . . the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill . . . to combine the elements in the way the claimed new invention does." *KSR Int'l v. Teleflex, Inc.*, 550 U.S. 398, 418 (2007). While the Supreme Court warned against "[r]igid preventative rules that deny factfinders recourse to common sense," it stated that the "factfinder should be aware . . . of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning." *Id.* at 421.

ANALYSIS

Claim 1

Appellants do not dispute the Examiner's findings that WO '045, Frantzen, and Boyle individually describe an implantable medical device comprising a metallic element, which *in vivo* includes a stabilized martensite phase and an austenite phase (FF 12-21). Rather, Appellants' position is based on the theory that the Examiner's rejections are in error because the prior art references do not disclose or suggest the "placement" of the

element in relation to areas of the body that would subject the stabilized martensite phase and the austenite phase to high strain and lesser strain, respectively.

We cannot agree with Appellants. Claim 1 is a device claim, not a process claim that recites a "placement" step. When properly construed in light of the Specification, claim 1 does not place any structural limitations on the shapes or dimensions of the two recited phases of the metallic element (FF 1-11). Hence, the prior art devices are indistinguishable, in terms of structure, to the claimed device.

Given the identity in the structures, it would reasonably appear that the prior art devices would perform the same function or possess the same characteristics attributed to the claimed device when deployed in a body in the same manner as that intended for the claimed device. That the prior art references might teach a different use for the same device as claimed is of no moment. *Schreiber*, 128 F.3d at 1478.

The burden was therefore shifted to Appellants to come forward with persuasive evidence demonstrating that the prior art devices would not inherently or necessarily perform the same or similar function, or possess the same characteristic, when deployed in a patient's body in the same manner as intended in claim 1. From a slightly altered perspective, the burden was on Appellants to show that the prior art devices could not be deployed in any part of a body such that the stabilized martensite portion would be subject to high strain and that the austenite portion would be subject to lesser strain. Appellants failed to meet their burden.

Appellants' failure to meet their burden is particularly pronounced here because they have urged emphatically that "high strain portions of an

element are easily locatable via deformation analysis as is extremely well known to those skilled in the art" (App. Br. 5-6). The agency, on the other hand, lacks the facilities to conduct experiments and/or the ability to expend funds to have these experiments performed. *Best*, 562 F.2d at 1255.

For these reasons, we find no error in the Examiner's rejection of claim 1 (as well as all claims falling therewith).

Claim 16

Appellants contend that none of WO '045, Frantzen, and Boyle teaches a device having a "super-elastic core portion . . . primarily formed of Nitinol" and a "fatigue-resistant surface portion primarily formed of Nitinol," as recited in claim 16. We agree with Appellants as to Frantzen but not as to WO '045 and Boyle.

Contrary to Appellants' belief, WO '045 plainly discloses a device in which "at least a portion of the implant" includes the same materials that Appellants refer to as the "super-elastic core portion" and the "fatigue-resistant surface portion" (FF 14). Similarly, Boyle teaches the provision of martensitic NITINOL regions on a cylindrical substrate having NITINOL deposited thereon (FF 21). Accordingly, we uphold the Examiner's factual findings that WO '045 and Boyle describe the disputed claim limitations (Ans. 9).

We next consider Frantzen. In response to Appellants' argument, the Examiner refers to Frantzen's column 3, lines 16-30 as teaching the claimed "super-elastic core portion" and "fatigue-resistant surface portion" (Ans. 8). But that teaching does not support the Examiner's position (FF 18). Thus,

we reverse the Examiner's rejection of claim 16 (and all claims dependent thereon) based on Frantzen.

CONCLUSION

On this record, we conclude that:

(1) the absence of disclosure in Frantzen, WO '045, or Boyle as to placement of the device in a body such that the stabilized martensite portion and the austenite portion are, during use, subjected to high strain and relatively lesser strain, respectively, does not preclude the Examiner's rejections of claim 1;

(2) WO '045 and Boyle, but not Frantzen, disclose or suggest a "medical implant comprising a structural element defining a shape of at least a portion of the implant," wherein a portion of the element is "a super-elastic core portion" and another portion is a "fatigue-resistant surface portion," as recited in claim 16.

DECISION

The Examiner's decision to reject:

Claims 1-8, 15-19, and 22 under 35 U.S.C. § 103(a) as unpatentable over WO '045;

Claims 1-8 and 15 under 35 U.S.C. § 103(a) as unpatentable over Frantzen;

Claims 2, 9-13, 20, and 21 under 35 U.S.C. § 103(a) as unpatentable over WO '045 in view of Flomenblit;

Claims 2 and 9-13 under 35 U.S.C. § 103(a) as unpatentable over Frantzen in view of Flomenblit;

Claims 1, 3-8, 14-19, 22, and 23 under 35 U.S.C. § 103(a) as unpatentable over Boyle; and

Claims 2, 9-13, 20, and 21 under 35 U.S.C. § 103(a) as unpatentable over Boyle in view of Flomenblit,

is affirmed.

However, the Examiner's decision to reject:

Claims 16-19 and 22 under 35 U.S.C. § 103(a) as unpatentable over Frantzen; and

Claims 20 and 21 as unpatentable over Frantzen in view of Flomenblit,

is reversed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED

bim

PATRICK J. FAY, ESQ.
FAY KAPLUN & MARCIN, LLP
SUITE 702
150 BROADWAY
NEW YORK, NY 10038